PARTNERING TO PROMOTE AN UNDERSTANDING OF ISO 15189:2003

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Quality Management Program — Laboratory Services

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ABSTRACT

Context: The Quality Management Program – Laboratory Services provides accreditation to ISO 15189:2003. Partnering with the Standards Council of Canada and the Entidad Mexicana de Acreditación, it developed a course to familiarize laboratory personnel with this international standard.

Objective: To illustrate ISO 15189:2003, recognize differences from other standards, know how to apply this standard, and how to assess conformance to it.

Methods: Two instructors delivered a five-day course utilizing lectures and group exercises. Sixteen presentations were delivered and seven group exercises conducted. A final written examination was administered.

Results: Twenty-four individuals attended the course in Mexico City from October 4-8, 2004. Lectures covered an introduction, background and overview of ISO 15189:2003 in medical laboratories, document/record control, uality manuals, measurement analysis and improvement, referrals, personnel, accommodation and environmental conditions, laboratory equipment/supplies, pre-examination procedures, examination procedures and quality assurance, post-examination procedures and reporting, safety, and assessment processes. Content was drawn from *Plus 15189 the ISO 15189:2003 essentials – a practical handbook for implementing the ISO 15189:2003 standard for medical laboratories* (Canadian Standards Association, 2004). Group exercises were incorporated throughout the five days. Case studies were used in the group exercises to highlight clauses within the standard, illustrate how they apply in practice, and demonstrate how to assess conformance to them. They reinforced the lecture content and focused on quality management systems, quality management and document control, measurement analysis and improvement, referrals, resources, pre-examination, quality control and post-examination. Comparisons were provided to ISO 9000:2000, 17025 and 15190. A final examination consisted of 26 true/false or multiple-choice questions and six conformity assessment scenarios. For each scenario, students identified at least one applicable conforming and one non-conforming clause from ISO 15189:2003. Certificates of completion were presented to all attendees.

Conclusions: A comprehensive course can be successfully delivered to familiarize laboratory personnel with ISO 15189:2003.

INTRODUCTION

Objectives of 15189 Course

- ❑ To familiarize participants with ISO 15189:2003
- ❑ To enable participants to recognize its differences from other standards
- ❑ To illustrate how to apply the standard (20% of content)
- ❑ To illustrate how to assess conformance to this standard and understand what to look for when assessing conformance 80% of content)

ISO 15189:2003

- ❑ Originally proposed in 1995, adopted by ISO in February 2003
- ❑ Intended Use:
  - In currently recognized disciplines of medical laboratory services
  - To improve medical laboratory structure and function
  - By accrediting bodies engaged in recognition of competence

Course Format

- ❑ Five-day live course, consisting of lectures, group exercises and a final examination
- ❑ Daily 9:00 - 17:00

COURSE CONTENT

Day 1 — 15189: Purpose, Intent and Application

Introductory Remarks

Icebreaker in groups of two. Interview a partner, then introduce your partner to the group

Presentation 1: Background to 15189
- ❑ ISO
- ❑ ISO 9000
- ❑ Health care and ISO
- ❑ Laboratory Quality
- ❑ ISO 15189 Development
- ❑ ISO 17025 and 15189
- ❑ ISO 15189 Application and Limitations

Presentation 2: Medical Laboratories
- ❑ Medical vs. other types of laboratories
- ❑ Clients of medical labs
- ❑ Referral of work
- ❑ Path of Workflow
- ❑ Point-of-care testing
- ❑ Progress in medical laboratories
- ❑ Special Considerations

Exercise A : Quality Management Systems
- ❑ What does the term "Quality Management System" mean?
- ❑ What are the elements of a quality system?
- ❑ How does it relate to the current practice in medical laboratories?

Presentation 3: Overview of 15189

Day 2 — 15189 Management Requirements: Conformance Assessment

Presentation 4: Document and Record Control
- ❑ Document identification
- ❑ Document creation, approval, review and revision
- ❑ Obsolete documents
- ❑ Records management

Presentation 5: The Quality Manual
- ❑ Basic structure and contents
- ❑ Use of the Quality Manual
- ❑ Example Quality Manual

Exercise B: Quality Management and Document Case Studies

Presentation 6: Measurement, Analysis and Improvement
- ❑ Complaints
- ❑ Non-conformities
- ❑ Corrective action
- ❑ Quality indicators
- ❑ Staff education
- ❑ Internal audits
- ❑ Management review

Exercise C: Measurement, Analysis and Improvement Case Studies

Presentation 7: Referral Laboratories
- ❑ Selection
- ❑ Competence assessment
- ❑ Records
- ❑ Reports

Day 3 — 15189 Laboratory Resource Requirements: Conformance Assessment

Exercise D: Referral Laboratories Case Studies

Presentation 8: Personnel
- ❑ Information on personnel
- ❑ Laboratory Director
- ❑ Training
- ❑ Competence assessment
- ❑ Authority of staff

Presentation 9: Accommodation and Environmental Conditions
- ❑ Laboratory space
- ❑ Design
- ❑ Environmental conditions
- ❑ Controlled access
- ❑ Communications
- ❑ Storage
- ❑ Separation
- ❑ Cleanliness

Presentation 10: Equipment, Reagents and Supplies
- ❑ Provision of equipment
- ❑ Equipment performance
- ❑ Equipment records
- ❑ Equipment safety
- ❑ Defective equipment
- ❑ Calibration
- ❑ Software

Exercise E: Resources Case Studies

Day 4 — 15189 Technical Requirements: Conformance Assessment

Presentation 11: Pre-Examination Phase
- ❑ Requisitions
- ❑ Specimen collection instructions
- ❑ Mislabelled specimens
- ❑ Specimen transport
- ❑ Compromised specimens
- ❑ Urgent and verbal requests

Exercise F: Pre-Examination Case Studies

Presentation 12: Examinations and Quality Assurance
- ❑ Workflow
- ❑ Validation and review of procedures
- ❑ Procedure manuals
- ❑ Reference intervals
- ❑ Quality control
- ❑ Uncertainty of measurement
- ❑ Verification of trueness
- ❑ Interlaboratory comparisons
- ❑ Multiple instruments

Presentation 13: Post-Analytical Phase
- ❑ Review of results
- ❑ Storage and disposal of specimens
- ❑ Reports – content, release, alterations
- ❑ Critical results
- ❑ Turnaround times

Day 5 — Laboratory Safety

Exercise G: Quality Assurance and Post-Analytical Case Scenarios

Presentation 14: Safety in the Medical Laboratory
- ❑ Safety issues in 15189
- ❑ Hazards in the medical laboratory
- ❑ Safe practices in the medical laboratory
- ❑ Safety-related equipment

Summary, questions

Exam

Wrap-up and course evaluations

Day 1

ISO 15189:2003 Management Requirements

- ❑ Organization & management
- ❑ Quality management system
- ❑ Document control
- ❑ Review of requests and contracts
- ❑ Referral laboratories
- ❑ External services and supplies
- ❑ Advisory services
- ❑ Resolution of complaints
- ❑ Identification and control of non-conformities
- ❑ Continual improvement
- ❑ Corrective action
- ❑ Preventive action
- ❑ Quality and technical records
- ❑ Internal audits
- ❑ Management review

ISO 15189:2003 Technicalt Requirements

- ❑ Personnel
- ❑ Accommodation and environmental conditions
- ❑ Laboratory equipment
- ❑ Pre-examination procedures
- ❑ Examination procedures
- ❑ Assuring the quality of examination procedures
- ❑ Post-examination process
- ❑ Reporting of results
- ❑ Alterations and amendments of reports

Sample Slide from Presentation 3

Day 2

Sample Case Study from Exercise C

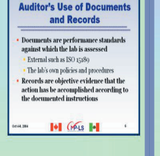
Clause 4.12.4 Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care. When this programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

Laboratory shows you many detailed and interesting reports of quality indicators, complete with graphical displays.

- ❑ Number of abnormal glucose results
- ❑ Number of positive blood cultures
- ❑ Number of smokers with lung cancer
- ❑ Number of antibodies in pregnancy
- ❑ Number of transfusions performed

Would you cite a non-conformance?

Sample Slide from Presentation 4



Day 3

Sample Case Study from Exercise D

Clause 4.5.1 The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology, and related disciplines. Laboratory management, with the advice of users of laboratory services where appropriate shall be responsible for selecting and monitoring the quality of referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.

Laboratory explains that they do not monitor the performance of consultants used for the referral of slides for morphological interpretation. They explain that the above standard is certainly not intended to include such consultants since it is contrary to the accepted professional etiquette among pathologists, and due to the fact that all pathologists know each other.

Would you cite a non-conformance?

Sample Slide from Presentation 10

Day 4

Sample Case Study from Exercise F

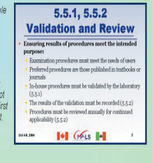
Clause 5.4.12

Sample portions shall also be traceable to the original primary sample.

Laboratory routinely separates off aliquots of serum from a single specimen to send to different analyzers or different areas of the laboratory for testing. Each aliquot is carefully labeled with both the first name and last name of the patient

Would you cite a non-conformance?

Sample Slide from Presentation 12



Day 5

Sample Case Study from Exercise G

Clause 5.8.1.4 The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Results provided verbally shall be followed by a properly recorded report.

5.8.1.5 Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

In laboratory A, physicians and nurses routinely telephone the laboratory for verbal reports. The laboratory's policy is to provide them with a verbal result, but it is simply too labour intensive to record the name of the person and the date and time.

Laboratory B has established a turnaround time for each examination. These were reviewed and accepted by a review panel compromised of laboratory staff and key users of laboratory services. During the audit of this laboratory, you speak to several physicians and nurses who remark that that turnaround times are not as fast as they would like.

Would you cite a non-conformance?

Sample Slide from Presentation 14

EXAM FORMAT

Format
- ❑ 2 hour time limit
- ❑ Open book: ISO 15189:2003 allowed but no course notes
- ❑ 50 marks
- ❑ Two independent grades averaged
- ❑ 70% required to pass

Two sections

Section I
- ❑ True/False and Multiple Choice
- ❑ 26 Questions
- ❑ One correct answer for each question
- ❑ One mark for each correct answer

Section II
- ❑ Conformity Assessment Scenarios
- ❑ Six scenarios, four marks each scenario
- ❑ Identify at least one 15189:2003 conforming clause (2 marks)
- ❑ Identify at least one 15189:2003 non-conforming clause (2 marks)

ACKNOWLEDGEMENTS

- ❑ Standards Council of Canada
- ❑ Entidad mexicana de acreditación, a.c.
- ❑ Inter-American Development Bank

RESULTS

- ❑ Course was delivered over 5 days
- ❑ Students did not require prior auditing knowledge
- ❑ Case studies reinforced how to assess conformance to the Standard
- ❑ Of 24 students, 96% successfully completed final exam on first try
- ❑ Certificates of completion were presented to all students